

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., :
LTD., :

Plaintiff, :

v. :

BARR LABORATORIES, INC., et al., :

Defendants. :

OTSUKA PHARMACEUTICAL CO., :
LTD., :

Plaintiff, :

v. :

SANDOZ INC., :

Defendant. :

OTSUKA PHARMACEUTICAL CO., :
LTD., :

Plaintiff, :

v. :

SUN PHARMACEUTICAL :
INDUSTRIES, LTD, :

Defendant. :

Civil Action No. 07-1267 (MLC)
Consolidated with: 07-1000 (MLC)

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Civil Action No. 07-1000 (MLC)

Civil Action No. 07-1516 (MLC)
Consolidated with: 07-1000 (MLC)

**OTSUKA PHARMACEUTICAL CO.,
LTD.,**

Plaintiff,

v.

**TEVA PHARMACEUTICALS USA,
INC., et al.,**

Defendants.

**Civil Action No. 07-1110 (MLC)
Consolidated with: 07-1000 (MLC)**

**OTSUKA PHARMACEUTICAL CO.,
LTD.,**

Plaintiff,

v.

**TEVA PHARMACEUTICALS USA,
INC., et al.,**

Defendants.

**Civil Action No. 07-2919 (MLC)
Consolidated with: 07-1000 (MLC)**

**OTSUKA PHARMACEUTICAL CO.,
LTD.,**

Plaintiff,

v.

APOTEX CORP., et al.,

Defendants.

**Civil Action No. 07-1346 (MLC)
Consolidated with: 07-1000 (MLC)**

**M E M O R A N D U M
O P I N I O N**

HUGHES, U.S.M.J.

This matter has come before the Court upon Motions from Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka" or "Plaintiff"), for leave to file a First Amended Complaint, for bifurcation of the willfulness issues from the liability issues after closing the pleadings, and

for a stay of discovery as to the willfulness issues and 35 U.S.C. § 271(a) infringement issues (“Motions”) [dkt. entry nos. 180, 181, 182, 183, 184, and 185], returnable November, 17 2008. Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (“Barr”), Sandoz, Inc. (“Sandoz”), Sun Pharmaceutical Industries, Ltd. (“Sun”), Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (“Teva”), and Apotex Corp. and Apotex, Inc. (“Apotex”) (collectively “Defendants”) filed opposition to the Motions on November 3, 2008. Plaintiff filed its reply in each case on November 10, 2008. The Court heard oral argument on the Motions on November 18, 2008 via recorded conference call.

I. BACKGROUND

A. Plaintiff’s Motions for leave to file a First Amended Complaint, for bifurcation of the willfulness issues from the liability issues after closing the pleadings, and for a stay of discovery as to the willfulness issues and 35 U.S.C. § 271(a) infringement issues

In this matter, Plaintiff seeks to update its infringement allegations and add a willful infringement count against all Defendants and add an infringement allegation under 35 U.S.C. § 271(a) against Apotex, Sandoz, and Teva. Plaintiff also seeks a bifurcation of the willfulness issues and the 35 U.S.C. § 271(a) infringement allegation from the liability issues after closing the pleadings as well as a stay of discovery as to the willfulness and 35 U.S.C. § 271(a) infringement issues.¹

Plaintiff contends that “[t]here has been neither bad faith nor undue delay on the part of Otsuka in filing [these] Amended Complaint[s] . . . [and the Defendants] will not be unduly prejudiced by the Amended Complaint[s] either.” (Pl.’s Br. at 3-4.) Plaintiff also contends that

¹ Since the Plaintiff’s moving papers are nearly identical, aside from the infringement allegation under 35 U.S.C. § 271(a) that Plaintiff seeks to add against Apotex, Sandoz, and Teva, the Court will cite to the Plaintiff’s motion against Sandoz [dkt. entry no. 181].

their “Amended Complaint[s] can certainly withstand a motion to dismiss, given that the proposed amendment sets forth more than sufficient factual allegations on which this Court may find willful infringement.” *Id.* at 4. Specifically, the Amended Complaints include allegations concerning Defendants’ extensive reckless activities relating to aripiprazole, continued pursuit of the infringing ANDA submission, baseless defenses concerning these infringing activities, deliberate copying of the teachings of the ‘528 patent claims, and litigation misconduct. *Id.* at 4-5. Plaintiff further states that “Courts have clearly and consistently held that there can be willful infringement in the context of ANDA litigation, when the allegations point to more than just the bare ANDA filing.” *Id.* at 5, citing *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, No. 05-CV-1887, 2005 U.S. Dist. LEXIS 39341, at *6 (D.N.J. Dec. 30, 2005). Lastly, Plaintiff argues that a bifurcation and stay of Otsuka’s proposed claims for willful infringement and 35 U.S.C. § 271(a) infringement would avoid prejudice to both Plaintiff and Defendants and ultimately “promote judicial economy and efficiency . . . [because] [i]t would avoid disruption of the present discovery schedule, while facilitating trial and adjudication of all issues.” *Id.* at 7-8.

B. Defendants’ Opposition

In response, Defendants maintain that the Motions to Amend should be denied since the proposed amendments are futile. *Marks v. Struble*, 347 F. Supp.2d 136, 150 (D.N.J. 2004). First, Defendants argue that willful infringement based on the filing of an ANDA is simply unavailable in a patent infringement suit based solely on 35 U.S.C. § 271(e)(1); thus, Otsuka’s baseless allegations of deliberate copying, baseless certifications, baseless pleadings and litigation misconduct cannot change this. Defendants also argue that the Federal Circuit has repeatedly confirmed that a claim for willful infringement is simply not available in a patent

infringement case predicated solely on an ANDA filing. *See Glaxo Group Ltd. v. Apotex Inc.*, 376 F.3d 1339, 1350 (Fed. Cir. 2004); *see also Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000).

Next, Defendants Apotex, Sandoz, and Teva argue that the allegations of commercial infringement under 35 U.S.C. § 271(a) are also futile because Otsuka fails to plead a claim for infringement and cannot prove any facts to support a claim of infringement under 35 U.S.C. § 271(a). Sandoz and Teva assert that bare legal conclusions without facts cannot satisfy the most broad interpretation of notice pleading, thus Plaintiff's bare claim that Sandoz and Teva infringed at least one claim of the '528 patent under 35 U.S.C. § 271(a) cannot withstand a motion to dismiss. Apotex maintains that because it has not offered aripiprazole for sale, Otsuka's 35 U.S.C. § 271(a) infringement allegations cannot withstand a motion to dismiss.

Furthermore, Defendants maintain that Otsuka waited until the eve of the deadline for amending the pleadings to make its intent to include a willfulness claim known and permitting such an amendment will place an unnecessary burden on and prejudice Defendants because they will be faced with delay and will be forced to defend against an enhanced damages allegation that is not permitted in *Hatch Waxman* cases. Lastly, Defendants argue that because Otsuka's actual infringement and willful infringement claims must fail, there is nothing to stay or bifurcate, therefore, Otsuka's requests must be denied.

C. Plaintiff's Reply

In reply, Plaintiff asserts that Otsuka has alleged a detailed course of conduct demonstrating Defendants' reckless disregard for Otsuka's patent rights, thereby establishing willful infringement. Plaintiff argues that "[u]nder *Seagate*, 'to establish willful infringement, a

patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent' [and] [t]his same approach necessarily applies to pleading and proving willfulness in an ANDA case" (Pl.'s Reply at 6) (quoting *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007)). Plaintiff further argues that Defendants misconstrue *Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacol, Inc.*, 231 F. 3d 1339 (Fed. Cir. 2000) and miss that "the Federal Circuit in *Yamanouchi* in fact affirmed the district court's decision in its entirety, including the district court's finding of willful infringement based on the defendant's baseless ANDA certification *and* litigation misconduct." *Id.* at 7 (quoting *Yamanouchi*, 231 F.3d at 1347-48). Plaintiff also asserts that it has provided the requisite specificity, consistent with the notice pleading standard to enable the Defendants to understand Otsuka's 35 U.S.C. § 271(a) infringement allegations. Plaintiff argues that should the Court accept the Defendants argument that the notice pleading standard has not been met, Otsuka will be denied a full and fair opportunity for discovery from Defendants to more precisely disclose basis of the claims. *Id.* at 4.

II. DISCUSSION

A. Federal Rule of Civil Procedure 15

It has been the accepted and encouraged policy that courts should liberally grant leave to amend pleadings, when justice so requires. FED. R. CIV. P. 15(a); *see also Koch Materials Co v. Shore Slurry Seal, Inc.*, 216 F.R.D. 301, 304-5 (D.N.J. 2003). The determination of a motion to amend falls within the discretion of the trial court and is guided by Rule 15(a). *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002). Therefore, when the movant's request to amend is "a proper subject of relief, he ought to

be afforded an opportunity to test his claim on the merits.” *Id.*

The United States Supreme Court has articulated this standard in *Foman*, which states, in relevant part:

In the absence of any apparent or declared reason - such as undue delay, bad faith, or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of the amendment, futility of amendment . . . , the leave sought should, as the rules require, be freely given.

Id.

In applying FED. R. CIV. P. 15(a), the Third Circuit Court of Appeals regards the possibility of prejudice to the nonmoving party as the “touchstone for the denial of the amendment.” *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993) (quoting *Cronell & Co., Inc. v. Occupational Safety and Health Review Comm’n*, 573 F.2d 820, 823 (3d Cir. 1978)). However, the nonmoving party has a heavier burden than merely claiming prejudice, it must show that an unfair disadvantage or deprivation will result by allowing the amendment. *See generally Heyl v. Patterson Int’l, Inc. v. R.D. Rich Housing of the Virgin Islands, Inc.*, 633 F.2d 419, 426 (3d Cir. 1981); *see also Deakyne v. Comm’rs of Lewes*, 416 F.2d 290, 300 n.19 (3d Cir. 1969).

“Prejudice,” for purposes of determining whether to allow the proposed amendment, involves serious impairment of the nonmovant’s ability to present its case. *Harter v. GAF Corp.*, 150 F.R.D. 502, 509 (D.N.J. 1993). Incidental prejudice to the nonmoving party is not a sufficient basis for denial of an amendment; prejudice becomes “undue” when the nonmoving party shows that it would be unfairly disadvantaged or deprived of the opportunity to present

facts or evidence that it would have offered. *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990); *DiLoreto v. Borough of Oaklyn*, 744 F. Supp. 610, 615 (D.N.J. 1990).

Leave to amend the pleadings may be denied on the grounds of bad faith, dilatory motive, or undue delay on the part of the moving party. See *Jablonski v. Pan American World Airways, Inc.*, 863 F.2d 289, 292 (3d Cir. 1992). The federal courts have often admonished the filing of vexatious litigation, even where the legal and factual grounds are not of a frivolous nature. *Aetna Life Insurance Co. v. Alla Medical Services, Inc.*, 855 F.2d 1470 (9th Cir. 1988). In short, parties to a litigation may not file motions to amend “primarily to cause harassment and delay.” See *Bygott v. Leaseway Transp. Corp.*, 637 F. Supp. 1433, 1447 (E.D. Pa. 1986).

B. Futility as a Basis of Denying a Motion to Amend

A court may deny a party leave to amend a pleading if the proposed amendment would be futile. See *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000) (citing *Smith v. NCAA*, 139 F.3d 180, 190 (3d Cir. 1998), *rev'd on other grounds*, 525 U.S. 459 (1999)). An amendment is futile if the pleading as amended would not survive a motion to dismiss for failure to state a claim upon which relief could be granted. *Id.*

To determine if an amendment would be futile, the court should apply the same standard of legal sufficiency as would be applied to a 12(b)(6) motion. See *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997) (citing *Glassman v. Computervision Corp.*, 90 F.3d 617, 723 (1st Cir. 1996)). When considering a motion to dismiss pursuant to 12(b)(6), the court shall take all allegations as true and consider them in the light most favorable to the nonmoving party. See *Brown v. Phillip Morris Inc.*, 250 F.3d 789, 795 (3d Cir. 2001). If an

amendment is not clearly futile, denial of leave to amend is improper. *See* 6 CHARLES ALLAN WHITE, ARTHUR R. MILLER, & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 1487 at 637-42 (2d ed. 1990) (footnotes omitted).

I. 35 U.S.C. § 271(e) Willful infringement

The Federal Circuit has ruled that the Hatch Waxman Act's highly artificial act of infringement [under 35 U.S.C. § 271(e)(2)] gives rise only to the limited set of statutorily-defined consequences set forth in 35 U.S.C. § 271(e)(4) and the allowable remedies do not include a declaration of willful infringement. *See Glaxo Group Ltd. v. Apotex Inc.*, 376 F.3d 1339, 1349 (Fed. Cir. 2004). Otsuka misconstrues *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000) when it states that "the Federal Circuit has affirmed an award of attorneys' fees because of a defective Paragraph IV Certification notice letter, that, according to the district court, amounted to willful infringement." (Pl.'s Br. at 5-6.) In *Yamanouchi*, the Federal Circuit explained that despite the fact that defendant had served both a baseless certification and numerous baseless filings at trial, the defendant nevertheless did not commit willful infringement because willful infringement is not an available remedy in infringement cases based solely on 35 U.S.C. § 271(e)(2). *See Yamanouchi*, 231 F.3d at 1347. Furthermore, in a recent opinion by Judge Wolfson, the Court emphasized that allegations of willful infringement are not appropriate in cases where infringement is based upon the filing of an ANDA and relevant paragraph IV certification. *See Celgene Corp. v. Teva Pharms. USA, Inc.*, No. 07-4459 (FLW) (D.N.J. Nov. 10, 2008). Therefore, the Court finds that Plaintiff's claims of willful infringement are futile.

ii. 35 U.S.C. § 271(a) Commercial infringement

“A plaintiff's obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1964-65 (2007). Plaintiff seeks to assert infringement pursuant to 35 U.S.C. § 271(a) with bare allegations such as, “deliberate copying of Otsuka’s patent claims, ongoing pursuit of [Defendant’s] infringing ANDA submission, filing of baseless Certification Notices, the pursuit of baseless litigation defenses and counterclaims, and litigation misconduct.” (Pl.’s Br. at 7.) The Court notes that copying in and of itself does not constitute infringement pursuant to 35 U.S.C. § 271(a).

Plaintiff’s proposed amendments include allegations that Defendants have (1) thwarted Otsuka’s requests for discovery but at the same time has demanded overbroad, excessive, and unnecessary discovery from Otsuka; (2) served overly broad document requests seeking excessive document discovery from Otsuka; (3) refused to produce any additional documents beyond its final ANDA concerning aripiprazole by the April 1, 2008 deadline; (4) failed to timely produce court-ordered discovery; (5) demanded an excessive number of depositions from Otsuka and from third-party witnesses, while refusing to timely make their own witnesses available for deposition. *See* Pl.’s Proposed Amended Complaints. In the Court’s eighteen years experience, such allegations have never been found to amount to “litigation misconduct” nor does the Plaintiff cite any case which would support such a conclusion, thus the Court cannot find litigation misconduct in this case on these grounds. Accordingly, the proposed claim here would be futile on the grounds that it does not state a claim for relief.

C. Prejudice

Defendants would suffer undue prejudice if the Court permitted Plaintiff's request to amend their Complaints. Indeed, the Defendants can show that "unfair disadvantage or deprivation will result by allowing the amendment" by the disruption of the scheduling in this case, in light of the fact that fact discovery has closed and a conference to discuss methods to streamline trial has been set for January 21, 2009. *See generally Heyl v. Patterson Int'l, Inc. v. R.D. Rich Housing of the Virgin Islands, Inc.*, 633 F.2d 419, 426 (3d Cir. 1981). The Plaintiff's proposed Amended Complaints fail to articulate a factual basis for Defendants' alleged infringement under 35 U.S.C. § 271(a) as required by *Twombly*; therefore, implying that Plaintiff is inappropriately seeking a second shot at discovery. Furthermore, Defendants will also be prejudiced by an additional willful infringement claim because such will not only cause Defendants to be faced with delay, but will also force Defendants to defend against an enhanced damages allegation that is not permitted in *Hatch Waxman* cases. In this case, the amendments, if permitted would prejudice the Defendants, and, therefore, the Court will deny the Motions to Amend on the alternate grounds of delay and prejudice.

D. **Motions for bifurcation of the willfulness issues from the liability issues after closing the pleadings, and for a stay of discovery as to the willfulness issues and 35 U.S.C. § 271(a) infringement issues**

In light of the Court finding that Plaintiff's claims of willful infringement and 35 U.S.C. § 271(a) infringement are futile, there is no need to address the Motions for bifurcation of the willfulness issues from the liability issues after closing the pleadings, and for a stay of discovery as to the willfulness issues and 35 U.S.C. § 271(a) infringement issues. Therefore, the Court denies the Motions for bifurcation and for a stay as moot.

III. CONCLUSION

For the reasons stated above, Plaintiff's Motions for leave to file a First Amended Complaint, for bifurcation of the willfulness issues from the liability issues after closing the pleadings, and for a stay of discovery as to the willfulness issues and 35 U.S.C. § 271(a) infringement issues are denied. An appropriate Order accompanies this Memorandum Opinion.

DATED: December 5, 2008